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(71) Applicant and

(72) Inventor: BARKER, Stephen, G., E. [GB/GB]; 16 Wilks
Gardens, Shirley, Surrey CR0 8UJ (GB).

(74) Agent: KING, James, B.; Kings Patent Agency Limited,
73 Farringdon Road, Greater London, London EC1M 3JQ
(GB).

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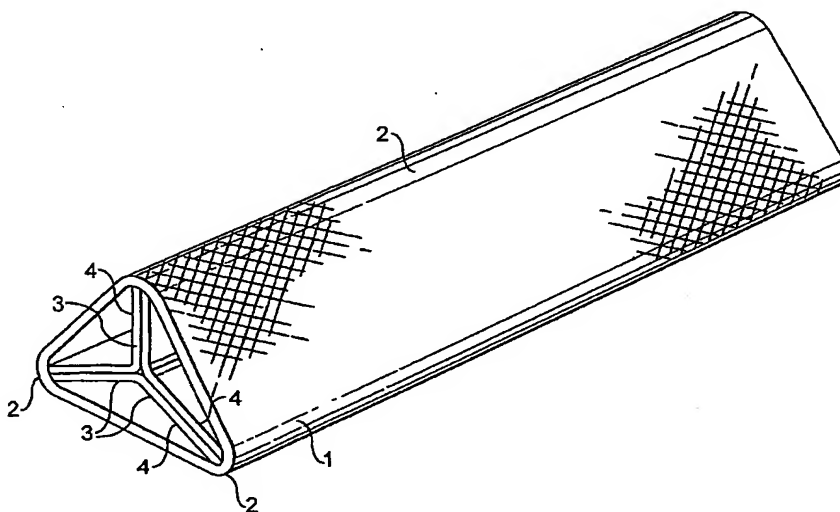
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ML, MR, NE, SN, TD, TG).

Published:
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*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: INGUINAL HERNIA REPAIR PROSTHESIS



(57) Abstract: An implantable prosthesis intended, primarily for the repair of muscle wall defects such as occur in inguinal hernias is fabricated from a surgically compatible mesh material having a prismatic external mesh wall (1). The prismatic shape includes three lobes (2), providing a generally triangular cross-sectional shape. The shape is maintained by internal reinforcing ribs (3), which here extend the length of the prism. The ribs are formed through the connection of three individual mesh strips (4), with each rib comprising two strip parts forming a lamination extending the length of the prism. With this construction closure of elongate legions is readily achieved and a wide range of elongate shapes and dimensions of hernias can be treated.

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Title:**Inguinal Hernia Repair Prosthesis**

This invention relates to an implantable prosthesis intended, primarily for the repair of muscle wall defects such as occur in inguinal hernias.

5 Prosthetic mesh materials are known for the repair and reinforcement of muscle walls. In one technique the mesh is formed into a conical shape forming a plug which is inserted in the hernia defect, often with placement of an additional sheet of flat mesh, to close the defect. In another form, shown in EP 0614650, there is disclosed a conical plug of a mesh material configured with
10 pleats and having inserted petal-like parts. This is stated to have an improved closure performance. The known devices are all useful for, and concerned with, closure of generally localised, or circular plan defects and it has been found that difficulties may occur when the defect opening has a more longitudinal dimension, as is seen with a direct inguinal hernia defect in
15 particular. Here, one or more conical or circular plan plugs is potentially unsatisfactory.

It is one object of this invention to provide an implantable prosthesis which performs to an enhanced degree for inguinal hernias having a more rectangular or elongate opening and in particular, for direct hernias..

20 According to this invention there is provided an implantable prosthesis for the repair of muscle wall defects such as occur in inguinal hernias, the prosthesis comprising a flexible plug of a surgically compatible mesh material, *characterised in that* the plug has an elongate form with one portion at least of the surface of the plug forming a projecting longitudinal ridge or bulge.

25 In a advantageous shape a portion of the surface of the plug may

comprise a projecting lobe formed by, or on, the surface. In a preferred arrangement the plug has a prismatic shape with a generally triangular cross-section.

In a preferred prosthesis according to this invention the cross-section of
5 the plug has a three lobed profile. The apices of the lobes may be joined by linear sides, providing a generally triangular cross-section. More than three lobes, or ridges, may be provided.

With a construction of this kind it has been found, surprisingly, that closure of elongate legions is readily achieved and the plug serves for closure
10 of a wide range of elongate shapes and dimensions of hernias.

The elongate mesh material forming the plug preferably has internal longitudinal support webs to support the profile of the mesh. These webs may be an integral part of the mesh configured by folding or formed by separate parts bonded to the inner surface of the outer profile. In another construction
15 three, or more, elongate sub-units may be connected to form the complete prosthesis. Such sub-units may themselves be of a triangular profile.

The wall of the mesh may be pleated circumferentially, or longitudinally to provide a degree of flexibility and compressibility, to facilitate placement into the defect comprising the hernia. For each requirement the mesh plug can be
20 cut to an appropriate required dimension from a stock length piece. This is in contrast to known prostheses which are of pre-determined dimensions whose size, for placement, must be judged carefully by the operating surgeon.

In an alternative construction the plug comprises a plurality of individual units connected in a longitudinal side-by-side relationship. Such units may
25 individually have a prismatic profile.

This invention also embraces a construction wherein the plug has an open side being in the form of a triangular profiled trough, the shape then being maintained by internal support formed by mesh material.

Hitherto, a size mis-match issue has proved difficult to resolve with
5 known plugs and the use of two or more plugs is expensive and can lead to unnecessary manipulation during the closure process, Hernia recurrence might occur. The present invention avoids such a basic problem and may be used with elongate and rectangular openings such as found, in particular, with direct inguinal hernia defects to which known plugs may provide an unsatisfactory
10 repair.

The mesh material may be polypropylene and any jointing required may be achieved, for example, by heat sealing. Materials and techniques for the manufacture of surgical mesh materials of the kind useful in carrying out this invention are well known in the art and are not therefore further described in
15 any more detail.

Embodiments according to this invention are described in more detail with reference to examples illustrated in the drawings. In the drawings:

Fig. 1 shows a first embodiment of a prosthesis with internal web support and according to this invention,

20 **Fig. 2** shows a second embodiment of prosthesis made from sub-units,
Fig. 3 shows a third embodiment of prosthesis with internal support, and
Fig. 4 shows a fourth embodiment with a further internal support.

Referring to Fig. 1, an implantable prosthesis intended, primarily for the repair of muscle wall defects such as occur in inguinal hernias is fabricated
25 from a surgically compatible mesh material having a prismatic external mesh

wall 1. The prismatic shape includes three lobes 2, providing a generally triangular cross-sectional shape. The shape is maintained by internal reinforcing ribs 3, which here extend the length of the prism, although discrete spaced ribs may be provided for certain applications. The ribs are formed
5 through the connection of three individual mesh strips 4, with each rib comprising two strip parts forming a lamination extending the length of the prism.

Fig. 2 shows a second embodiment according to this invention wherein the prism 20 is formed from three sub-units 21 (shown separated here), with
10 each sub-unit 21 having a triangular shape in cross-section. The sub-units 21 are joined by suitable and known techniques to form the complete prosthesis.

The embodiment shown in Fig. 3, is a variation of that shown in Fig. 1 where the internal supporting ribs comprise two back-to-back L-shaped supports, with the base limbs 31 lying on the lower internal side of the prism
15 and the vertical limbs 30 extending together to the upper lobe 32. Lateral reinforcement 33 may be provided.

Fig. 4 shows a construction similar to Fig. 3 but here the base limbs 31 of the two L-shaped supports 30 extend around the internal profile of the opposed lobes 33 and 34.

20 In all the embodiments, and according to a feature of this invention, the mesh material may be ridged, pleated, crumpled, or folded to stiffen or pad out the prosthesis this being with particular reference to the internal supports or webs.

In each case, the plug device is intended, primarily for placement into
25 (direct) inguinal hernia defects. From stock lengths, the device can be cut

exactly to the correct size. The plug can be sutured into place, or tissues sutured over to hold it in place. The plug may be used with a second, flat, overlying piece of mesh to thus form a tension-free repair.

In contrast to known conical plug devices which, when used together,
s have gaps between the apices allowing gut penetration, the present invention provides a single elongate plug which can be cut to size thus providing better closure and more resistance to penetration by the gut.

Claims:

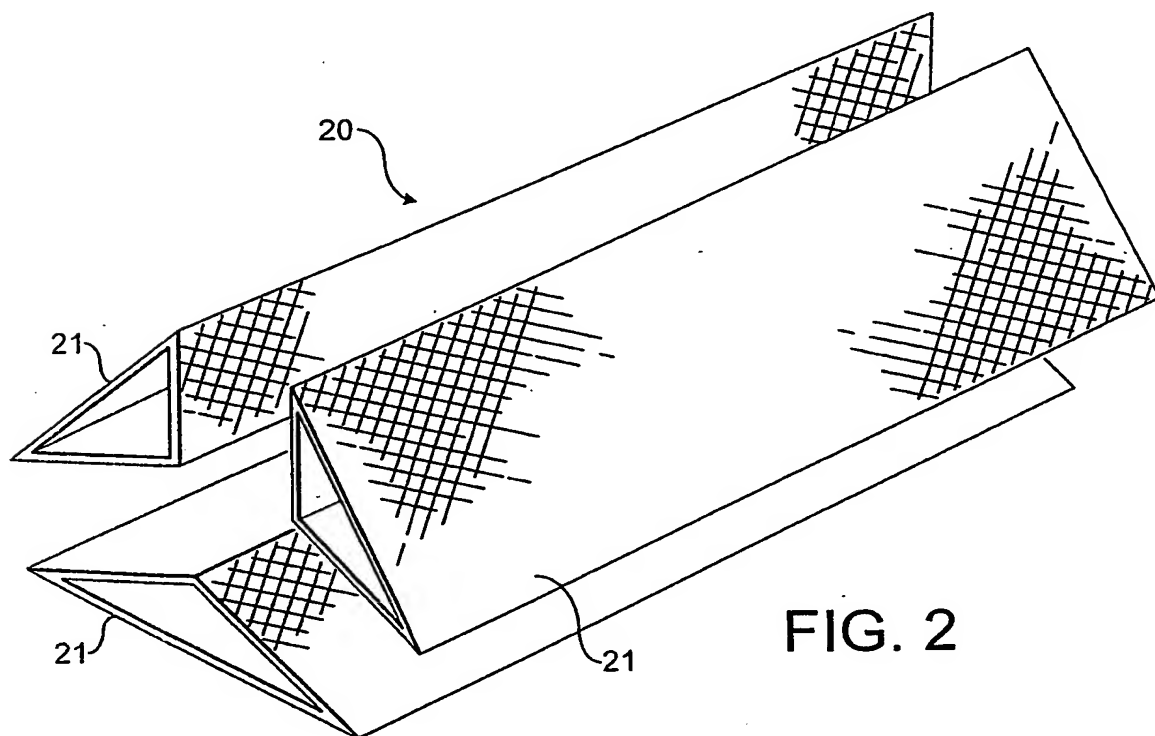
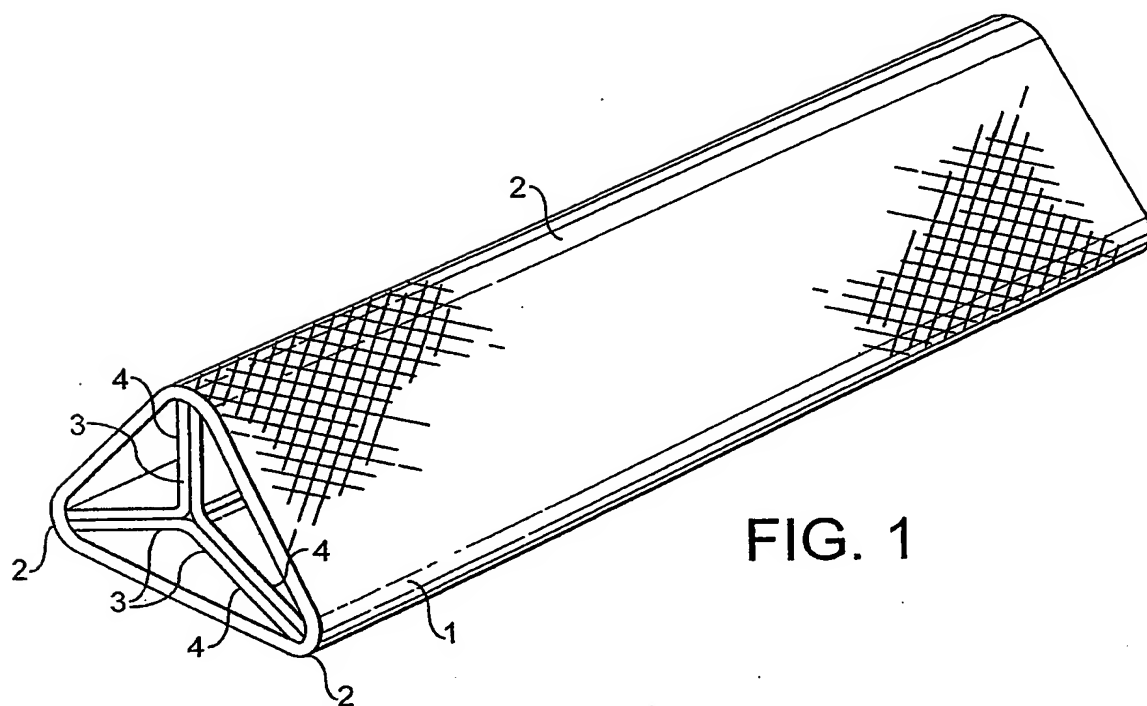
1. An implantable prosthesis for the repair of muscle wall defects, the prosthesis comprising a flexible plug of a surgically compatible mesh material, *characterised in that* the plug has an elongate form with one portion at least of the surface of the plug forming a projecting longitudinal ridge or bulge.
2. An implantable prosthesis in accordance with claim 1, wherein the said portion of the surface of the plug comprises a projecting lobe formed by, or on, the surface.
3. An implantable prosthesis in accordance with claim 1 or 2 wherein the plug has a prismatic shape with a generally triangular cross-section.
4. An implantable prosthesis in accordance with any preceding claim, wherein the cross-section of the plug has a three lobed profile.
5. An implantable prosthesis in accordance with claim 4, modified in that more than three lobes, or ridges, are provided.
6. An implantable prosthesis in accordance with claim 4 or 5, wherein the apices of the lobes are joined by linear sides, providing a generally triangular cross-section.
7. An implantable prosthesis in accordance with any preceding claim, wherein the elongate mesh material forming the plug has internal longitudinal webs to support the profile of the mesh.
8. An implantable prosthesis in accordance with claim 7, wherein the webs

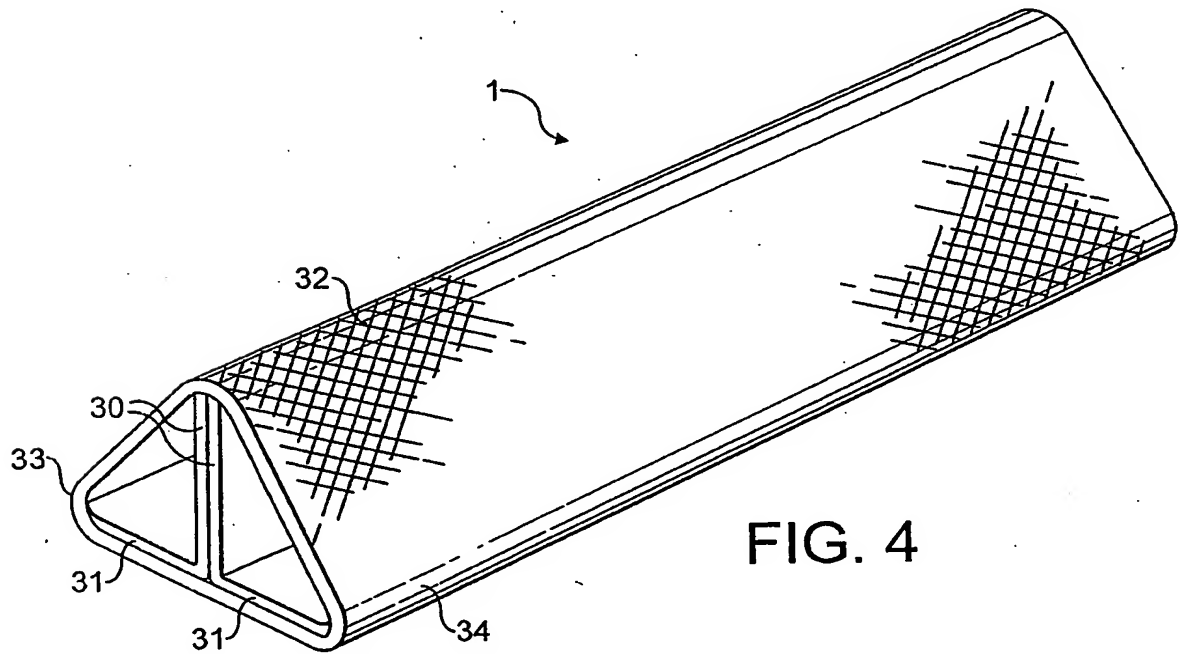
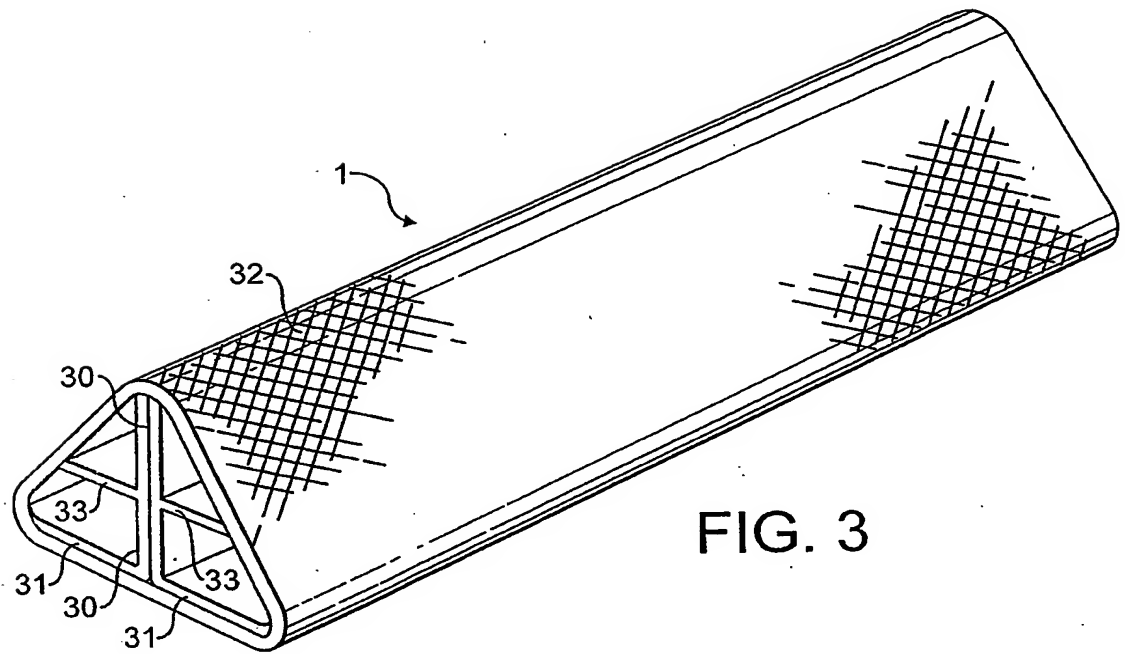
are an integral part of the mesh configured by folding or formed by separate parts bonded to the inner surface of the outer profile.

9. An implantable prosthesis in accordance with any preceding claim, wherein three, or more, elongate sub-units are connected to form the prosthesis, said sub-units preferably being of a triangular profile.
10. An implantable prosthesis in accordance with any preceding claim, wherein the wall of the mesh is pleated circumferentially, or longitudinally to provide a degree of flexibility and compressibility, to facilitate placement into a defect comprising a hernia.
11. An implantable prosthesis in accordance with any preceding claim, adapted whereby the mesh plug may be cut to an appropriate required dimension from a stock length piece.
12. An implantable prosthesis in accordance with any preceding claim, formed by a plurality of individual units connected in a longitudinal side-by-side relationship, preferably with such units individually have a prismatic profile.
13. An implantable prosthesis in accordance with any preceding claim, modified whereby the plug has an open side being in the form of a triangular profiled trough, the shape being maintained by an internal support formed by mesh material.
14. An implantable prosthesis in accordance with any preceding claim, wherein the mesh material comprises polypropylene with jointing, if required, achieved by heat sealing.
15. The use of an implantable prosthesis in accordance with any preceding claim for the treatment of elongate or rectangular openings such as are

found with i/nguinal hernia defects.

16. An implantable prosthesis as described herein and exemplified with reference to the drawings.





INTERNATIONAL SEARCH REPORT

PCT/GB2004/000078

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61F2/00 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 810 536 A (COUSIN BIOTECH) 28 December 2001 (2001-12-28) abstract; figure 2	1,2,5,9, 11
X	WO 03/002029 A (ETHICON INC) 9 January 2003 (2003-01-09) abstract page 6, line 23 -page 7, line 9; figure 8	1,2,10, 11,14
A	EP 0 614 650 A (BARD INC C R) 14 September 1994 (1994-09-14) cited in the application column 1, line 35 -column 2, line 14	1,14
P,X	WO 03/011181 A (BELLON CANEIRO JUAN MANUEL ;BUJAN VARELA JULIA (ES); LOPEZ HERVAS) 13 February 2003 (2003-02-13) abstract; figures 1-7	1-3,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

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Date of mailing of the international search report

12/05/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax (+31-70) 340-3018

Authorized officer

Newman, B

INTERNATIONAL SEARCH REPORT

PCT/GB2004/000078

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15, 16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☒ Claims Nos.: 16
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16

No features in the claim itself. Claim relying on references to drawings (Rule 6.2 (a) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

PCT/GB2004/000078

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